

The Claims:

1. A process for providing a dosage form, wherein the process comprises the steps as follows:

(a) blending an osmotic hydrogel and an osmotically effective solute to provide a composition that increases in volume in the presence of an aqueous fluid;

(b) blending a hydroxyalkylcellulose and water to provide a granulation solution;

(c) spraying the granulation solution (b) onto the composition provided in (a) to provide granules;

(d) blending a drug, a surfactant, and a member selected from the group consisting of a mono- and di-glyceride to provide a drug formulation;

(e) adding the drug formulation (d) to a capsule;

(f) adding the sprayed composition of (c) to the capsule;

(g) coating the capsule with a semipermeable composition to provide a membrane permeable to an aqueous fluid; and,

(h) providing an exit in the membrane (g) for delivering the drug at a sustained-release and controlled rate over an extended time from the dosage form.

2. The process for providing the dosage form according to Claim 1, wherein step (b) precedes step (a).

3. The process for providing the dosage form according to Claim 1, wherein step (f) precedes step (e).

4. The process for providing the dosage form according to Claim 1, wherein the membrane (g) comprises a cellulose acetate and polyethylene glycol.

5. The process for providing the dosage form according to Claim 1, wherein drug formulation comprises polyoxyl 35 castor oil and acetylated monoglyceride.

6. The process for providing the dosage form according to Claim 1, wherein the drug (d) comprises a member selected from the group consisting

of a peptide, protein, protein anabolic hormone, growth promoting hormone, endocrine system hormone, porcine growth promoting hormone, bovine growth promoting hormone, equine growth promoting hormone, human growth promoting hormone, hormone derived from a pituitary gland, hormone
5 derived from a hypothalamus gland, recombinant DNA, samatotropin, gonadotropic releasing hormone, follicle stimulating hormone, luteinizing hormone, LH-RH, insulin, colchicine, chlorionic gonadotropin, oxytocin, vasopressin, desmopressin, adrenocorticotrophic hormone, prolactin, bypressin, thyroid stimulating hormone, secretin, pancreozymin, enkephalin
10 and glucagon.

7. The process for providing the dosage form according to Claim 1, wherein the membrane (g) comprises a thermoplastic polymer composition possessing a softening point of 40° C to 180° C.

8. The process for providing the dosage form according to Claim 1,
15 wherein the drug formulation (d) comprises an emulsion drug formulation.

9. The process for providing the dosage form according to Claim 1, wherein the drug formulation (d) comprises a two-phase emulsion and comprises an agent that imparts emulsification to the drug formulation comprising a member selected from the group consisting of
20 polyoxyethylenated castor oil comprising 9 moles to 52 moles of ethylene oxide, polyoxyethylenated sorbitan monopalmitate comprising 20 of ethylene oxide, polyoxyethylenated sorbitan monostearate comprising 20 moles of ethylene oxide, polyoxyethylenated sorbitan monostearate comprising 4 moles of ethylene oxide, polyoxyethylenated sorbitan tristearate comprising
25 20 moles of ethylene oxide, polyoxyethylenated sorbitan monostearate comprising 20 moles of ethylene oxide, polyoxyethylenated sorbitan trioleate comprising 20 moles of ethylene oxide, polyoxyethylenated stearic acid comprising 8 moles of ethylene oxide, polyoxyethylene lauryl ether, polyoxyethylenated stearic acid comprising 40 moles to 50 moles of ethylene
30 oxide, polyoxyethylenated stearic acid comprising 50 moles of ethylene oxide, polyoxyethylenated stearyl alcohol comprising 2 moles of ethylene oxide, and polyoxyethylenated oleyl alcohol comprising 2 moles of ethylene oxide.

10. The process for providing the dosage form according to Claim 1, wherein drug formulation is an emulsified formulation comprising a member selected from the group consisting of a vegetable, mineral, animal and marine oil, an ester of an unsaturated fatty acid, a monoglyceride, a diglyceride, a triglyceride, an acetylated glyceride, olein, palmitin, stearin, lauric acid hexylester, oleic acid, oleyester, glycolyzed ethoxylated glycerides of oils, fatty acids comprising 13 molecules of ethylenoxide, and oleic acid declyester.

11. The process for providing the dosage form according to Claim 1, wherein drug formulation self-emulsifies.

ADD AI

[illegible]